K090751

Attachment IV.2 – 510(k) Summary (revised)

OCT 2 8 2009

General Information

Owner's Name:	Apollo Spine
Address:	307 Placentia Ave, Suite 111 Newport Beach CA 92663
Telephone Number:	(949) 645-7746
Fax Number:	(949) 645-7749
Contact Person:	Kamran Aflatoon
Subject Device Name:	Comet Anterior Cervical Plate System
Trade Name:	Comet Anterior Cervical Plate System
Common/Usual Name:	Anterior Cervical Plate System
Classification Name:	KWQ – Spinal Intervertebral Body Fixation Orthosis 21 CFR 888.3060; Class II
Predicate Device Name:	Comet Anterior Cervical Plate System
Trade Name:	Comet Anterior Cervical Plate System
Common/Usual Name:	Anterior Cervical Plate System
Classification Name:	KWQ – Spinal Intervertebral Body Fixation Orthosis 21 CFR 888.3060; Class II
Premarket Notification:	K082504, SE date January 27, 2009
Predicate Device Name:	Synthes Anterior Cervical Plate System
Trade Name:	Synthes Anterior Cervical Plate System
Common/Usual Name:	Anterior Cervical Plate System
Classification Name:	KWQ – Spinal Intervertebral Body Fixation Orthosis 21 CFR 888.3060; Class II
Premarket Notification:	K926453, SE date Oct. 12, 1993

Device Description

Multi-level anterior cervical plates and fixation screws are being added to the previously cleared single-level Comet Anterior Cervical Plate System. The multi-level device additions consist of dual-level plate lengths ranging from 24mm through 48mm and triple-level plate lengths ranging from 36mm through 72mm. Similarly to the single-level devices, the multi-level devices contain barbed plate fixation pins that are permanently affixed to the plate. Plate fixation screws are used to secure the plate to each vertebrae. An additional plate fixation screw diameter is being added in a 3.3mm diameter in 14mm, 16mm and 18mm lengths.

Indications for Use

The indications for use for the multi-level device additions are the same as those for the previously cleared single-level devices of the Comet Anterior Cervical Plate System. The indications are as follows:

The Comet Anterior Cervical Plate System is intended for anterior fixation, immobilization and stabilization of adjacent cervical vertebral bodies as an adjunct to intervertebral fusion by autogenous and/or allogenic bone graft.

The Comet Anterior Cervical Plate System is indicated for anterior cervical fixation (levels C2-C7) for the following indications: degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Performance Testing

Performance data demonstrated that the multi-level device additions to the Comet Anterior Cervical Plate System are substantially equivalent to the predicate single-level devices of the Comet Anterior Cervical Plate System and/or met pre-determined acceptance criteria. The risks associated with use of the new devices were found acceptable when evaluated by FMEA.

Bench tests performed in accordance with FDA's May 2004 *Guidance for Industry and Staff Spinal System 510(k)s* and ASTM F1717-04 *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model* included assessments of static and dynamic axial compression bending and static torsion.

No biocompatibility testing was conducted; all materials used in the manufacture of the Comet Anterior Cervical Plate System device have been previously cleared for similar devices.

Conclusion

The Comet Anterior Cervical Plate System multi-level device additions meet all the pre-determined acceptance criteria of the testing performed to confirm safety and effectiveness; the Comet Anterior Cervical Plate System multi-level device additions are substantially equivalent to the predicate device, the single-level devices of the Comet Anterior Cervical Plate System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Apollo Spine
% STD MED, Inc.
Ms. Christie Santagate
75 Mill Street
Stoughton, Massachusetts 02072

OCT 2 3 2009

Re: K090751
Trade/Device Name: Comet Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: October 19, 2009
Received: October 22, 2009

Dear Ms. Santagate:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment IV.1 – Indications for Use Statement (revised)

510(k) Number (if known): K090751

Device Name: Comet Anterior Cervical Plate System

Indications for Use:

The Comet Anterior Cervical Plate System is intended for anterior fixation, immobilization and stabilization of adjacent cervical vertebral bodies as an adjunct to intervertebral fusion by autogenous and/or allogenic bone graft.

The Comet Anterior Cervical Plate System is indicated for anterior cervical fixation (levels C2-C7) for the following indications: degenerative disc disease (defined as neck pain of disogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090751